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Appendix B

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510(k) Summary

Submitter Name	OMNIlife science, Inc. 50 O'Connell Way Suite #10 East Taunton, MA 02718	Contact: Christine Nassif Regulatory Affairs Phone: 774-226-1871 Fax: 508.822.6030
Submission Date:	July 11, 2011	
Trade Name	The Apex Knee System, Apex All Poly Tibia	
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	
Regulatory Class	Class II per 21 CFR § 888.3560	
Product Code	JWH	
Device Description	The Apex All Poly Tibia is used as part of a primary or revision cemented total knee implant using established total knee arthroplasty procedures. The All Poly Tibia is intended for use with bone cement, single use implantation and for use only with the Apex Knee™ System Femoral and Patella components. The device is machined from compression molded Ultra High Molecular Weight Polyethylene (UHMWPE per ASTM F648). This device is a semi-constrained monoblock tibia and designed for posterior cruciate substitution.	
Indications for Use	The Apex Knee™ System, Apex All Poly Tibia: The Apex All Poly Tibia is intended for use as part of a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate: • Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis; • Rheumatoid arthritis; • Correction of functional deformity; • Revision procedures where other treatments or devices have failed. The Apex All Poly Tibia is for use only with the Apex Knee™ System Femoral and Patella components. The Apex All Poly Tibia is indicated for cemented use only.	
Legally Marketed Predicate Device(s)	• Smith & Nephew Genesis II Total Knee System, K002740 • Apex Knee™ System, K060192	

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Predicate Device Comparison

	Apex All Poly Tibia (subject device)	Smith & Nephew Genesis II Total Knee System [K002740]	Apex Knee™ System [K060192]
Body Site	Knee	Knee	Knee
Intended Use	Primary or revision total knee replacement (cemented)	Primary or revision total knee replacement (cemented)	Primay or revision total knee replacement (cemented for Ultra Congruent)
Patient Population	Skeletally mature patients.	Skeletally mature patients.	Skeletally mature patients.
Similar Design and Specifications			
Device Design [component]	All Polyethylene Tibia	All Polyethylene Tibia	Apex Knee™ System – Ultra Congruent Tibial Component: Tibial insert Tibial Baseplate (asymmetrical)
Sterility	Ethylene oxide SAL 10^{-6} Residuals: ISO 10993-7	Ethylene oxide	Ethylene oxide SAL 10^{-6} Residuals: ISO 10993-7
Shelf Life	5 years from date of manufacture	Not Available	5 years from date of manufacture
MATERIALS and Standards			
Tibia Component(s)	Machined from compression molded UHMWPE (ASTM F648)	UHMWPE (ASTM F648)	Machined from compression molded UHMWPE(ASTM F648) CoCr Baseplate

Non Clinical Test Summary

The following tests were conducted:

- FEA Contact Stress Testing
- Stress Analysis
- Peg Stiffness Analysis
- Cement Mantle Stress Analysis
- FEA Abrasive Wear
- Insert Contact Pressure and Contact AreaTesting (ASTM F2083-08)

All samples tested met the acceptance criteria.

Clinical Test Summary

No clinical studies were performed.

Conclusion

The Apex Knee™ System, Apex All Poly Tibia is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OMNIlife science, Inc.
% Ms. Christine Nassif
Director, Regulatory Affairs
50 O'Connell Way, Suite #10
E. Taunton, Massachusetts 02767

JUL 13 2011

Re: K111062
Trade/Device Name: Apex Knee System, Apex All Poly Tibia
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: April 15, 2011
Received: April 18, 2011

Dear Ms. Nassif:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A

Indications for Use Statement

510(k) Number: (if known): K111062

Device Name: Apex Knee™ System, Apex All Poly Tibia

Indications for Use

The Apex Knee™ System, Apex All Poly Tibia:

The Apex All Poly Tibia is intended for use as part of a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed.

The Apex All Poly Tibia is for use only with the Apex Knee™ System Femoral and Patella components. The Apex All Poly Tibia is indicated for cemented use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111062